

REMARKS

The Examiner is thanked for the due consideration given the application. A declaration is being filed with this amendment.

Claims 21-41 are pending in the application. Claim 41 is newly presented and generally corresponds to subject matter found in claims 28 and 37.

No new matter is believed to be added to the application by this Amendment.

Rejections Based on COUGOULIC

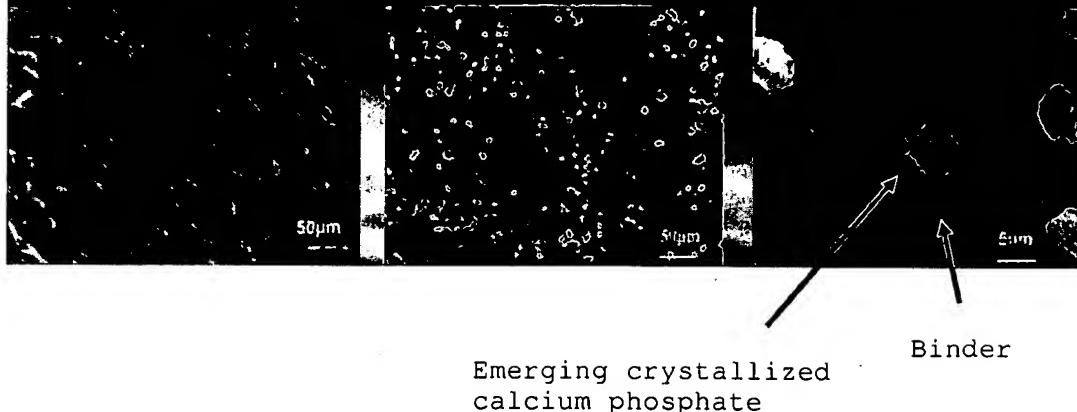
Claims 21-24, 26, 27, 39 and 40 have been rejected under 35 USC §102(b) as being anticipated by COUGOULIC (U.S. Patent 5,872,159). Claim 25 has been rejected under 35 USC §103(a) as being unpatentable over COUGOULIC in view of ELLINGSEN et al. (U.S. Publication 2002/0111694). Claims 28-38 have rejected under 35 USC §103(a) as being unpatentable over COUGOULIC in view of MILLS et al. (U.S. Patent 6,482,584).

These rejections are respectfully traversed.

The present invention pertains to a material for medical or veterinary usage that is formed from calcium phosphate and polymer biocompatible binder. The surface of this material is provided with emerging crystallized calcium phosphate. The emerging crystallized calcium phosphate can be seen in the photomicrograph reproduced below.

**Microgeometry:** it governs the cellular answer.

It is completely different between a molded or manufactured material. Below,SEM of BIOPIK® during surface treatment.



Independent claim 21 of the present invention recites:  
65% to 90% by weight of a polymer biocompatible binder and 10% to 35% by weight calcium phosphate, said material having a surface provided with emerging crystallized calcium phosphate.

COUGOULIC pertains to a material in the form of a molded piecework, made of 65 to 90 % in weight of a biocompatible binder and 10 to 35 % in weight of at least one compound for adding calcium and phosphorus.

COUGOULIC fails to disclose or infer a provided with emerging crystallized calcium phosphate, such as is set forth in independent claims 21 and 28 of the present invention.

As evidence thereof (which is also set forth in the accompanying declaration), there are presented results obtained by Scanning Electron Microscopy of the material with all the

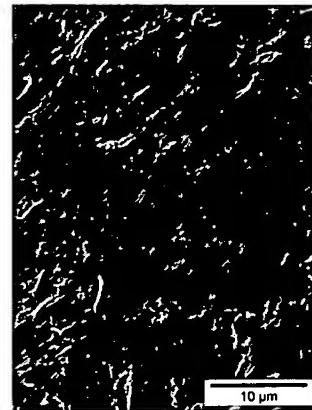
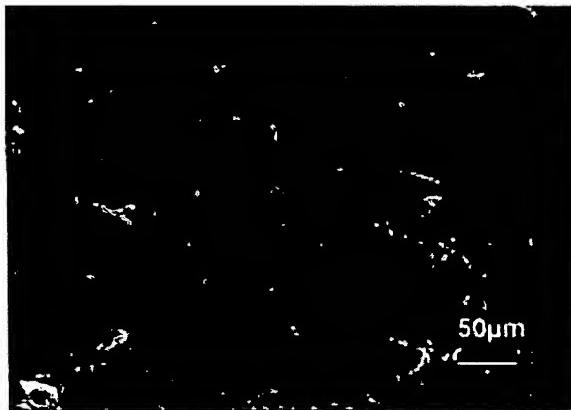
claimed ingredients after autoclaving, without and with prior surface treatments.

The corresponding material is here made of the following ingredients :

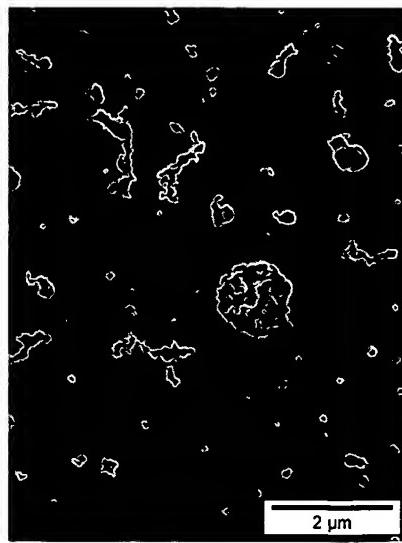
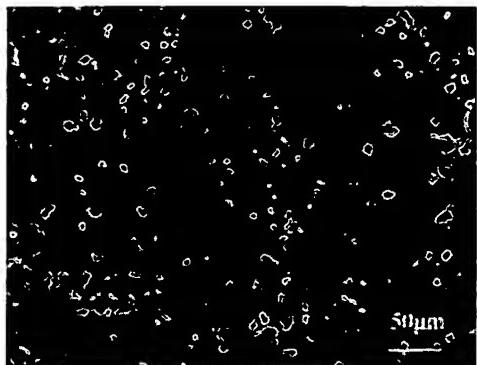
- 80% PEEK
- 10% TiO<sub>2</sub>
- 8% tricalcic phosphate
- 2% calcium hydroxyapatite

The material was formed by injection molding

a/ Material corresponding to Cougoulic prior art, with only sterilization by autoclave (but without prior surface pickling/decontamination treatments):



b/ Material according to the invention, i.e. COUGOULIC with surface pickling/decontamination treatments and then autoclave :



The molded material (a), corresponding to COUGOULIC, is provided with a surface composed of biocompatible binder.

Moreover, the calcium phosphates integrated in the matrix are not in a crystallized state.

***The COUGOULIC material of the prior art, only due to the claimed ingredients, is thus not provided with the emerging crystallized calcium phosphates.***

In contrast, the material (b), according to the present invention, is provided at its surface with the emerging crystallized calcium phosphate.

These photos and analyses obtained by Scanning Electron Microscopy show thus clearly that the emerging crystallized calcium phosphates of the material are not inherently achieved by a composition with all the claimed ingredients.

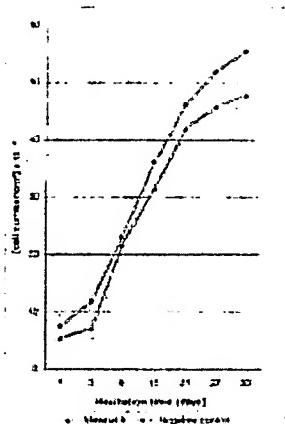
***Only the material according to the present invention is provided with such emerging crystallized calcium phosphates.***

Moreover, the inventor showed that the surface of the material in accordance to the present invention, is interesting in that it confers some particularly efficient integration characteristics to the surrounding tissue, better than the ones of the material not having such emerging crystallized calcium phosphates.

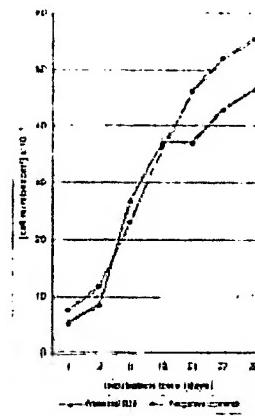
These characteristics are confirmed by the attached LEMI study, with the following products:

- Material B(ii) : Material according to COUGOULIC;
- Material A and B(i) : Material of the invention (these materials differ just due to the type of PEEK used).

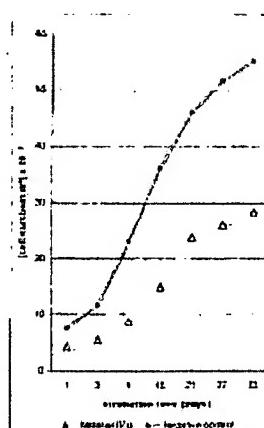
Please see in particular results 4.1.2 - Cell proliferation:



**Material A**  
Cells culture (human osteoblast) on material according to the invention (CE norms) with the surface treatment, versus same negative control



**Material B(i)**  
Cells culture (human osteoblast) on material according to the invention (US norms) with the surface treatment, versus same negative control



**Material B(ii)**

Cells culture (human osteoblast) on COUGOULIC material (i.e. without the surface treatment), versus same negative control.

These results also show that the material of the invention is different from COUGOULIC, and should be regarded as new and patentable.

Due to these reasons, the activated material according to the present invention should be regarded as new and inventive, compare to COUGOULIC (and also to the other applied art references).

As has been discussed in the amendment dated October 16, 2008, the technical problem for one skilled in the art would be to activate the surface and to optimize the integration characteristics in the surrounding tissue, of the molded material described in the closer prior art of COUGOULIC.

But, one skilled in the art would not have any reason to activate the surface of such material by providing it with emerging crystallized calcium phosphate.

In particular, none of the prior art documents teaches or infers such a surface characteristic.

Moreover, none of the prior art documents would be implicitly provided with such emerging crystallized calcium phosphate.

Also, newly presented claim 41 sets forth a method that includes pickling and decontamination processes. At least two points are advantageous to optimize this process:

- the successive steps of the surface pickling and decontamination operations,

- the surface pickling and decontamination operations on the molded piecework are made before the sterilization operation by autoclave.

As mentioned above, the material treated only by autoclave does not have any emerging crystallized calcium phosphate.

Moreover, please find below a photo obtained by Scanning Electron Microscopy of the material with all the claimed ingredients, treated only by surface pickling/decontamination without autoclaving.



Turning to MILLS et al., this reference describes a process that includes mainly in applying, onto the material, cleaning mixtures for biologic substrates simultaneously with negative / positive pressures (see Table I and II).

This is clearly different from surface pickling/decontamination operations before the sterilization operation by autoclave, as claimed in the present invention.

Even if MILLS et al. disclose the cleaning reagents used in the process claimed now, MILLS et al. do not teach to use the specific reagents combination claimed, or the specific claimed sequence.

Thus, in our view, MILLS et al. do not disclose the two main characteristics of the surface treatment of the present invention. The teaching of this document would thus not be sufficient to obtain the surface pickling/decontamination operations as claimed now, and then the implementation of the autoclave treatment onto this pickled material.

The process disclosed in MILLS et al. would be totally changed to obtain the one of the present invention, and one skilled in the art would not have any reason to perform these changes.

ELLINGSEN et al., used to reject claim 25, does not address the deficiencies of COUGOULIC discussed above.

COUGOULIC thus fails to anticipate a claimed embodiment of the present invention. One of ordinary skill and creativity would thus fail to produce a claimed embodiment of the present invention from a knowledge of COUGOULIC and the secondary references. A *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

CONCLUSION

The rejections are believed to have overcome obviated or rendered moot, and no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

- Declaration Under Rule 132 by Jean-Pierre Cougoulic with  
attached LEMI Report